Supreme Court, U.S.
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No. 92-1989

In The Supreme Court Of The United States

October Term, 1992

Jennifer Stamps,

Petitioner,

v.

The Collagen Corporation,

Respondent.

On Petition for Writ of Certiorari to the
United States Court of Appeals for the Fifth Circuit

Brief of Alabama, Alaska, American Samoa, Arizona, Arkansas, Connecticut, Delaware, Florida, Hawaii, Idaho, Indiana, Massachusetts, Minnesota, Missouri, Nevada, New Mexico, North Carolina, North Dakota, Northern Mariana Islands, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont, Wisconsin, and Wyoming as Amici Curiae in Support of Petitioners

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Pursuant to Rule 37 of the Rules of this Court, Alabama, Alaska, American Samoa, Arizona, Arkansas, Connecticut, Delaware, Florida, Hawaii, Idaho, Indiana, Massachusetts, Minnesota, Missouri, Nevada, New Mexico, North Carolina, North Dakota, Northern Mariana Islands, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont, Wisconsin, and Wyoming as amici curiae, respectfully submit this brief in support of the petitions for writ of certiorari submitted by Jane King in No. 92-1979 and Jennifer Stamps in No. 92-1989.[1]

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[1]Amici have submitted, under separate cover, identical briefs on both petitions, and refer in both briefs to the decisions of both the First and Fifth Circuit Courts of Appeals and to both the King and Stamps petitions.

Statement of Interest

The Courts of Appeals for the First and Fifth Circuits have decided that the States may not provide their citizens with tort law remedies for injuries caused by dangerous medical devices.

These decisions nullify the States' historic reliance upon tort law as the principal protection for their citizens from unsafe conduct and conditions. State tort law both compensates injured individuals, paying their medical and other expenses, and provides a powerful incentive to those who engage in potentially dangerous activities to minimize the risks of those activities. Through long processes of court decision and legislative action, the States have developed and refined their tort systems to balance the needs and rights of victims against the needs and rights of manufacturers of potentially dangerous products, such as the product that caused the injuries in these cases.

Where, as here, the States have exercised their basic powers to protect the health and welfare of their citizens, the federal courts must presume that there is no preemption of state action unless preemption is the "clear and manifest" intent of Congress. *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

The States submit this brief in order to assist this Court in reviewing the petitions, and to urge this Court, in light of this presumption against preemption and the specific circumstances of this case, to restore to the States the ability to provide tort remedies to their citizens who have been injured by dangerous medical devices.

Summary of Argument

The Courts of Appeals have decided that the safety measures employed by private manufacturers of medical devices are, when approved by the FDA, and in some cases, even when they are not approved by FDA, federal requirements that preempt state law. Their decisions go far beyond this Court's decisions in this area, which have only found preemption of state safety-related law where the federal government itself has enacted a safety standard.

The decisions of the Courts of Appeals deprive persons injured by the most dangerous class of devices of their state tort law remedies for those injuries. The impact of this decision will be profound. Not only will persons injured by dangerous devices have no legal remedy for their injuries, but the amount of safety that users of all medical devices can expect will be severely diminished. The FDA's premarket approval process is inadequate to ensure device safety, both because it is an imperfect process based upon incomplete information, particularly about long term and less common safety hazards, and because the removal of possible state tort law liability creates incentives for manufacturers to be less than candid with the FDA about known safety hazards.

The decisions of the Courts of Appeals are based upon the mistaken belief that Congress, as a matter of policy, intended premarket approval to be the maximum protection provided to the public. The plain language of the statute itself undermines this misconception by providing for more stringent regulation by the states.

In reaching their decision, the Courts of Appeals ignored this Court's admonitions to interpret express preemption provisions of statutes primarily in light of the language of the statute itself. The plain language of the statute indicates that only state laws specifically relating to a particular medical device are preempted, and that state laws of general applicability, such as the common law of torts, are not.

This plain language interpretation is consistent with the interpretation of the statute adopted by the FDA when it promulgated its preemption regulations and with the interpretation of the only state supreme court to have considered the issue. The interpretations of the Courts of Appeals conflict with both the FDA's and the state supreme court's interpretations.

Finally, the Courts of Appeals decided that all of the petitioners' state law causes of action are preempted, including their breach of warranty and fraud claims. However, the statute at issue here is very similar to the statute at issue in *Cipollone v. Liggett Group, Inc.*, 505 U.S. ___, 112 S.Ct. 2608, 2618 (1992), which this Court held did not preempt causes of action based upon breach of warranty or fraud.

In sum, the Courts of Appeals have adopted a novel interpretation of a federal preemption statute. Their interpretation is contrary to the plain language of the statute, conflicts with both FDA and state court interpretations of the statute, and deviates from one of this Court's recent interpretations of a similar statute. Considering the dramatic impact that their interpretation will have upon the rights of persons injured by medical devices and the safety of the medical device using public, this Court should review this case and restore to the States their ability to provide their citizens with tort remedies for injuries caused by dangerous medical devices.

Argument

I. This Court should determine that federal approval of a manufacturer's medical device specifications does not preempt state tort law causes of action.

The Courts of Appeals have interpreted the Food, Drug, and Cosmetic Act as stripping away essentially all legal remedies for persons who are injured by class III medical devices, the most dangerous class of medical devices.[2] In place of those remedies, they have installed the Food and Drug Administration's ("FDA") premarket approval procedures as the sole source of public protection from these devices.

This interpretation of the medical device provisions of the Food, Drug and Cosmetic Act, which have not yet been considered by this Court, greatly impacts the health and well being of medical device consumers. It will not only prevent the petitioners here from obtaining redress for their injuries, but will prevent all persons who are injured by dangerous medical devices from being compensated for their injuries. Moreover, the Courts of Appeals' reliance upon premarket approval procedures to protect the public health is fundamentally misplaced, as those procedures alone are inadequate to ensure that class III medical devices are safe.

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[2] 21 U.S.C. §360c(a)(1) establishes 3 classifications for medical devices: Class I, Class II, and Class III. Briefly, class I devices are devices for which the general provisions of the Act regarding misbranding, adulteration, good manufacturing practice and other matters are sufficient to provide reasonable assurance of safety and efficacy. Examples of class I devices include ice bags, tongue depressors, examination gloves, and crutches.

Class II devices are devices for which the general controls applicable to class I devices are insufficient to provide a reasonable assurance of safety and effectiveness, and for which there is enough information about the device to establish a special performance standard to provide that assurance. Examples of class II devices include: clinical electronic thermometers, intravascular catheters, and piston syringes.

Class III are devices which present too great a risk to be class I devices and for which insufficient information exists to establish a class II performance standard. Examples of class III devices include: replacement heart valves, intaocular lenses (for implantation into the eye), and contraceptive intrauterine devices (IUDs).

The impact of the Court of Appeals' decisions on the lives of persons who use medical devices is tremendous. This Court should consider and definitively determine the scope of preemption in the medical device area.

a. Federal approval of a manufacturer's medical device specifications is not a federal requirement that triggers preemption of state law.

This Court has not considered whether the kind of federal activity at issue here gives rise to preemption. The Courts of Appeals, without much analysis, held that FDA approval of a manufacturer's premarket application is a federal "requirement" which triggers preemption of state law. In fact, the role of the FDA in this area is substantially different from the federal role in other cases where this Court has found federal safety related activity to preempt state law. For example, in both *Cipollone* and *CSX Transportation, Inc. v. Easterwood*, 113 S.Ct. 1732 (1993), this Court's most recent pronouncements concerning federal health and safety requirements and state tort law, this Court found preemption where the federal government promulgated a safety standard with which compliance was mandatory. In *Cipollone*, Congress required specific warning statements to be included in cigarette advertising. In *CSX Transportation*, the Federal Railroad Administration set specific speed limits that were to be observed by railroad operators. In both cases, preemption was triggered by a specific standard promulgated by the federal government.

By contrast, the FDA's role with respect to an application for premarket approval is to merely determine, as a matter of fact, whether the application meets the statutory criteria for approval. If the application meets the criteria, then it must be approved. 21 U.S.C. § 360e(d). The specifications for the design, manufacture, and labeling of the device are set forth by the manufacturer in the application and they are solely the manufacturer's responsibility. 21 U.S.C. § 360e(c).

A manufacturer has broad discretion in how it structures its device specifications to meet the criteria for approval. If a device presents a particular safety hazard, a manufacturer, depending upon the nature of the hazard, may choose from a variety of options in minimizing the hazard. The manufacturer may redesign the device to eliminate the hazard, include a warning in the labeling of the device so that users may avoid the hazard, limit the indications for use of the device so it is not used in a manner that gives rise to the hazard, or take some combination of those actions. As long as the option chosen by the manufacturer supports a finding by the FDA that there is a "reasonable assurance that the device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling" of the device, then the FDA must approve the manufacturer's application. 21 U.S.C. § 360e(d)(1)(A).

Once a manufacturer has obtained FDA approval, it is free to make substantial safety related modifications to the device without first submitting those modifications to the FDA for review. 21 C.F.R. § 814.39(d) permits the following changes to be made without prior approval of the FDA:

> i. Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction.
>
> ii. Labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device.
>
> iii. Labeling changes that delete misleading, false, or unsupported indications.
>
> iv. Changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

By virtue of the nature of the premarket approval process and these regulations concerning post-approval modifications, device manufacturers have great latitude within which they can establish and modify their own substantive safety

specifications. By contrast, the cigarette manufacturers subject to federal warning requirements and the railroad operators subject to federal railway speed limits have no such discretion. For them, the federal government has established a substantive standard, from which they may not vary.

The device manufacturer's safety-related undertakings do not resemble federal safety standards so much as they resemble the undertakings of a warrantor who determines what characteristics a product will have and promises that the product will live up to those characteristics. In *Cipollone*, this Court held that an express warranty, because it was an undertaking of the manufacturer, was not a government requirement. *Cipollone*. at 2622. The same rationale should apply in this case. Because of the freedom accorded to manufacturers to pick and choose the safety measures they will include in their applications for premarket approval, those measures should not be treated as federal safety requirements that preempt state law.

b. The federal medical device approval process does not adequately protect the public health and should not serve as the public's sole protection from dangerous medical devices.

The devices which must be submitted for premarket approval, class III devices, must be so submitted because they present a potentially unreasonable risk of illness or injury and because their workings and effects on the human body are not well understood. 21 U.S.C. § 360c(a)(1)(C). Class III devices have not been generally used in medical practice, and there is no wide body of experience from which judgments of safety can be made. By definition, there is not enough information concerning these devices for the FDA to be able to promulgate a class II performance standard that would give a reasonable assurance of safety. 21 U.S.C. § 360c(a)(1)(C)(i)(II).[3] As result, the

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[3]It is useful to contrast the devices at issue here to the federal railroad speed limits at issue in *CSX Transportation*, and the federal health warnings at issue in *Cipollone*. With over one hundred years of experience with railroad transportation, it may fairly be said that railroad speed limits may be

FDA must act on an application for approval of a class III device without complete information about the safety of the device. In particular, it is most often without information about long term and less common side effects.

Typically, the FDA relies upon clinical studies, in animals and humans, to attempt to judge the safety of a proposed device. *See* 21 C.F.R. § 814.20 (required contents of application, with extensive discussion of requirements for clinical studies). Unfortunately, no clinical study can reliably identify all of the possible side effects, particularly the long range side effects, of a new device. Such studies are generally conducted only for a relatively short term and with a relatively small number of subjects. While they are useful in determining the gross effects of a device on the human body, they are not as reliable in detecting less common effects or effects which only manifest themselves over the long term. The FDA itself recognizes the inherent difficulties in relying upon clinical studies to determine the safety of devices, and as a result, almost always requires post-approval monitoring of problems that arise in connection with the actual use of devices in the marketplace. Because of the limitations on the information available for the kinds of devices that must go through the premarket approval process, it is not surprising that once a device is approved and marketed widely, significant safety hazards may be discovered.

The case at bar graphically illustrates the problems that can arise when a device is approved without complete information concerning the safety hazards it presents. Zyderm was approved for use by the FDA in 1981. However, it was not

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determined with a reasonable degree of confidence that the limits will ensure safety. Similarly, federal cigarette warnings were not promulgated until after years of scientific and public debate about the effects of smoking on health. By contrast when the FDA receives an application for approval of a brand new medical device, the hazards of the device are not entirely known, and the appropriate measures to minimize those hazards are also not well understood. In that environment, it is difficult to be confident that the approval process will ensure a desired level of safety. This Court should hesitate before ascribing to the premarket approval procedure the power to prevent future injuries to such an extent that it is no longer necessary to provide for a system of compensation for those injuries which do occur.

until several years later that a link between Zyderm and the disorder at issue here, dermatomyositis or polymyositis ("DM/PM"), was suspected. The linkage between DM/PM and Zyderm was primarily established by post-approval epidemiological evidence, which by its very nature can only be examined after a device has been widely used. In fact, the first published, peer reviewed study concerning this link did not appear until June of 1993, 12 years after Zyderm was initially approved by the FDA.[4] Because the information connecting DM/PM and Zyderm was unavailable to the FDA at the time of Zyderm's approval, the approval process provided no protection at all for the victims of this disorder.

Even if the FDA were able to know about all of the possible hazards presented by a device at the time the device is presented for approval, the premarket approval process has other shortcomings that render it inadequate as the sole source of public protection against dangerous devices.

The FDA cannot, as part of the premarket approval process, determine that a manufacturer will not negligently or intentionally alter the design, manufacture or labeling of a device in some way that might create a safety hazard. The FDA cannot ensure that a manufacturer will not negligently or intentionally make false or misleading statements about a device in advertising. Nothing in the premarket approval process provides any assurance that a manufacturer will conduct itself without negligence or other tortious conduct after its device has been approved. Indeed, given these facts and the freedom granted to manufacturers to make safety related changes to their devices after they have been approved, users of medical devices can never really be assured that the device they are using is the same as the device that was reviewed by the FDA.

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[4]Cukier, Beauchamp, Spindler, Spindler, Lorenzo, and Trentham, *Association between Bovine Collagen Dermal Implants and a Dermatomytosis or a Polymyositis-like Syndrome*, 118 Annals of Internal Medicine, June 15, 1993, at 921.

Because of the inherent difficulties in attempting to determine all of the risks posed by a particular device and the problems associated with monitoring manufacturer conduct after the device has been approved, FDA approval of the device provides only a minimum assurance of safety.[5] The Courts of Appeals have elevated this minimum assurance to the maximum assurance of safety that the public can have. This Court should intervene to preserve the measures that the States have taken to provide their citizens with additional protection.

c. State tort law is the only source of compensation for persons injured by dangerous medical devices and provides incentives for manufacturers to ensure safety both during the federal approval process and afterward.

The incentives provided by the state tort system make the premarket approval process work. The potential of tort liability for a serious safety defect provides an incentive for manufacturers to test their products thoroughly and to provide complete data to the FDA. It similarly motivates them to engage in rigorous post-marketing surveillance so that they will be alerted to any undiscovered safety hazards in as timely a manner as possible. These incentives are important, because without them, the regulatory scheme creates perverse incentives to suppress information about safety hazards.

In the environment created by the Courts of Appeals, a manufacturer of a Class III device need only look to the FDA for permission to market its device. As long as the FDA has approved the device and that approval is not withdrawn, the manufacturer may profitably market the device. That source of profit is jeopardized by any negative safety information that

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[5]This is not to say that FDA approval is useless. It serves as a vitally important screening point to eliminate the thousands of blatantly fraudulent, inadequately tested and quack devices that would flood the marketplace were FDA approval not a prerequisite for marketing all but the most innocuous (class I) or well understood (class II) devices. The point of this discussion is that as the sole source of public protection from class III devices, FDA approval is inadequate.

might cause the FDA to disapprove an application for premarket approval or to withdraw a previously granted application. While certainly most reputable manufacturers would still act upon negative safety information, there would be no sanction for manufacturers who either negligently or intentionally fail to do so. In such cases, the FDA's premarket review process would become a bureaucratic shell game with little real protective value.

In addition, as discussed above, there are situations in which a manufacturer can make significant safety related changes to an approved device or its labeling without seeking additional prior approval from the FDA. While the regulation permitting these changes is intended to permit manufacturers to immediately act upon safety problems that slip past premarket review or that are discovered after approval is given, they provide no protection for the public if manufacturers make these changes, either negligently or intentionally, in ways that cause additional injuries to consumers of devices. Only state tort laws impose duties with respect to these product changes.

Finally, and most importantly, the tort law system is the only mechanism by which persons injured by devices can be compensated for their injuries. Even where the federal government has taken over exclusive responsibility for ensuring safety in a particular industry, as is the case in the civilian nuclear power industry, this Court has been reluctant to deprive individual citizens of tort remedies for injuries resulting from that industry's activity. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

The Courts of Appeals have determined that manufacturers of Class III devices should be free of state tort liability. In so doing the Courts of Appeals have created a regulatory climate in which persons injured by dangerous medical devices have no legal remedy for their injuries and in which the sole protection for users of such devices is an imperfect FDA review process, which is itself undermined by the perverse incentives created by the elimination of tort

liability. In so doing, the Courts of Appeals have strayed beyond the reach of *Cipollone* and *CSX Transportation*. They have extended federal preemption of state safety law to areas where the federal government has not enacted its own safety standards, but has merely approved the safety standards of private manufacturers. Because this case raises both important safety issues and an unsettled extension of federal preemption law, this Court should grant the petitioner's request for review.

II. This Court should review the decisions below because they are inconsistent with this Court's Supremacy Clause jurisprudence and create judicial and administrative agency conflicts that only this Court can resolve.

a. The Courts of Appeals based their decisions on presumptions which conflict with the plain language of the express preemption provision here, in contravention of this Court's admonitions that express preemption provisions be interpreted by their own terms.

The touchstone for determining Congressional intent to preempt must be the language of the statute claimed to have preemptive effect, particularly when that statute contains an express preemption provision. *CSX Transportation, Inc.*, at 1737, *Cipollone*, at 2618.

However, instead of following to their logical and natural conclusion the basic principles of statutory construction employed by this Court, the Courts of Appeals, particularly the First Circuit, constructed their own views of congressional intent upon which they based their own erroneous interpretations of the statute.

The First Circuit, relying upon legislative history which had nothing to do with the preemption provision at issue, determined that the Congressional purpose was to establish FDA requirements as the maximum protection to be afforded the individual user. *King v. Collagen Corp.*, 983 F.2d 1130, 1138 (1st Cir. 1993). The court then concluded that the statutory language conformed to its view of congressional intent. *Id.*

The First Circuit's approach not only ignores this Court's established principles of statutory interpretation, the policy prescription upon which it is based is at odds with the language of the statute.

The savings clause in 21 U.S.C. § 360k(b) provides that the FDA may exempt state requirements from preemption if the state requirement "is more stringent than a requirement under this Act...." It is highly unlikely that Congress intended subsection (a) of 21 U.S.C. § 360k to establish the FDA's requirements for devices as the maximum level of public protection when in subsection (b) of the same provision it authorized states to enact and maintain more stringent requirements for devices. Clearly, as both Stamps and King argued to the Courts of Appeals, FDA requirements are minimum requirements which can be augmented by state requirements. The interpretations of the statute by the Courts of Appeals should not have been biased by the misconception that Congress intended premarket approval to be the maximum protection afforded the public.

Stripped of the policy bias adopted by the Courts of Appeals, the most natural reading of the statute here preempts only state requirements that are targeted at a specific device, such as hearing aid regulations, rather than requirements of general applicability, such as the common law of torts. This conclusion flows from the specific words used in the device preemption provision of the Food, Drug and Cosmetic Act. That provision provides:

> [N]o State...may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device....

21 U.S.C. § 360k(a).

Webster's New Collegiate Dictionary defines "respect" as "a relation to or concern with something usually specified" and defines "respecting" as "in view of" and "with regard to."

WEBSTER'S NEW COLLEGIATE DICTIONARY 986 (1977). The common law of torts does not have any specified relationship with "a device," nor was it developed in view of or with regard to "a device." Therefore, if the phrase "with respect to a device" is to be given its plain dictionary meaning, the common law is not a "requirement with respect to a device."

In reaching a contrary interpretation of the scope of preemption, the Courts of Appeals ignored the difference between the phrase "with respect to," used by Congress to describe the state requirements preempted, and the word "applicable," used by Congress to describe the federal requirements that trigger preemption. Webster's defines "applicable" as "capable of or suitable for being applied," and supplies the following example: "There are several statutes applicable to the case." *Id.* at 54. The interpretation of the Courts of Appeals is supportable if one substitutes the phrase "applicable to" for the phrase "with respect to" in the statute. Certainly, the common law of torts is applicable to devices. If Congress had intended to include state requirements that are merely applicable to a device, then it could have used "applicable to" in place of "with respect to," as it did in the clause of the provision describing the federal requirements triggering preemption. Congress's choice to use a narrower phrase to describe the state laws within the scope of preemption than the phrase it used to describe the federal laws triggering preemption should be given effect.

That Congress did not intend preemption of general state laws that have no reference to a medical device is further reinforced by the use of the word "device" in the singular. Had Congress intended to preempt generally applicable state laws, it would more likely have used the phrase "with respect to devices" rather than "with respect to a device." Moreover, the phrase "federal requirement applicable under this chapter to the device" uses the word "the device" to refer back to the device referenced by the preempted state requirement. This reference back to the specific device regulated by state law

makes no sense when applied to the general common law, as the common law makes no reference to any medical device.

In their rush to validate their own policy presumptions, the Courts of Appeals failed to adequately consider the import of the preemption language used by Congress. As evidenced by that language, Congress did not intend to preempt common law tort causes of action.

b. The decisions of the Courts of Appeals conflict with the FDA's preemption regulations and with a recent decision of the Supreme Court of Hawaii.

The decisions of the Courts of Appeals are, as discussed at length in the King Petition at 13-15, inconsistent with the FDA's regulation implementing 21 U.S.C. §360k and with the decision of the Supreme Court of Hawaii in *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273 (Hawaii 1992).

The FDA has determined, as is argued herein, that only state requirements specifically directed at devices are preempted. In adopting its regulations implementing the preemption provision of the statute, it determined that "State or local requirements of general applicability where the purpose of the requirement relates...to other products in addition to devices..." are not preempted. 21 C.F.R. § 808.1(d).

In *Larsen* the Supreme Court of Hawaii determined that premarket approval is not a federal requirement that triggers preemption under the statute. The court reviewed the federal regulations concerning premarket approval and concluded that they merely set forth general procedural requirements which did not trigger preemption analysis under the statute.[6] *Larsen*, at 1282.

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[6] The *Larsen* case, like this case, provides another example of a safety hazard discovered after FDA approval. *Larsen* involved an approved pacemaker that was recalled after it was discovered that it malfunctioned at temperatures slightly above normal body temperature. The plaintiff in Larsen endured several surgeries, including major open heart surgery, and life threatening complications in order to replace his FDA approved pacemaker.

The interpretations of the FDA and the Supreme Court of Hawaii conflict with the interpretations of the Courts of Appeals. This conflict can only be resolved by this Court.

c. The Courts of Appeals analyzed the breach of warranty and fraud claims in these cases in contravention of the principles set forth in this Court's *Cipollone* decision.

Even if this Court were to determine that Congress intended to preempt common law causes of action in this area, the conclusion of the Courts of Appeals that common law actions for fraud, misrepresentation, and breach of warranty are preempted directly conflicts with this Court's holding in *Cipollone*.

The preemption provision at issue in *Cipollone* and the provision at issue here are similar in that both statutes preempt state "requirements." In *Cipollone*, this Court held that the requirements upon which a breach of warranty claim is based are imposed by the manufacturer, not the state, and therefore are not state "requirements." *Cipollone*, at 2633. There is no basis for distinguishing this case. The requirements upon which the breach of warranty claims here are based are imposed by Collagen upon itself, not by the states, and therefore are not preempted state "requirements."

Stamps' and King's fraud and misrepresentation claims should also be found not to be preempted. In *Cipollone*, this Court distinguished between requirements arising out of a duty not to deceive, and requirements arising out of a duty to make such warnings as are necessary to make a product reasonably safe. *Cipollone*, at 2624. The Court held that only the latter class of requirements were preempted because they related to "smoking and health." The Court held that because fraud and misrepresentation claims arose out of a duty not to deceive rather than a duty relating to smoking and health, fraud and misrepresentation claims were not preempted. *Id.*

In this case, only requirements relating to the "safety and efficacy" of a device are preempted. 21 U.S.C. § 360k(a). This

language is essentially the same as that in the Public Health Cigarette Smoking Act, and should be similarly construed to preempt only requirements arising out of a duty to warn of unreasonable safety hazards. Requirements arising out of a generalized duty to be truthful should not be preempted.

In sum, the Courts of Appeals have adopted a novel interpretation of a federal preemption statute. Their interpretation is contrary to the plain language of the statute, conflicts with both FDA and state court interpretations of the statute, and deviates from one of this Court's recent interpretations of a similar statute. Considering the dramatic impact that their interpretation will have upon the rights of persons injured by medical devices and the safety of the medical device using public, this Court should review this case and restore to the States their ability to provide their citizens with tort remedies for injuries caused by dangerous medical devices.

Conclusion

For the foregoing reasons, the Petitions for Writ of Certiorari should be granted.

Respectfully submitted,

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